REMARKS/ARGUMENTS

Status of the Application

In the August 29, 2006, Non-Final Office Action, claims 25, 27-30, 32, and 34 were rejected. In the present response, no amendments to the claims were made.

Rejections Under 35 U.S.C. § 101

Claims 25, 27-30, 32, and 34 were rejected under 35 U.S.C. § 101 because the claimed invention is allegedly not supported by either a substantial asserted utility or a well-established utility. Applicants respectfully traverse these rejections.

For an invention to have utility "at least one specific, substantial, and credible utility" must be either disclosed in the specification or well-established for the invention. Utility Examination Guidelines, 66 Fed. Reg. 1092, 1094 (Jan. 5, 2001). Based upon this standard, it is respectfully submitted that the present rejection under 35 U.S.C. § 101 for lack of utility is improper because at least one specific, substantial, and credible utility for the present application is asserted or is well-established. The utilities of the present application include 1) membership in a class of proteins that share a specific, substantial, and credible utility; 2) non-endogenous expression of polynucleotides of the present invention; 3) antisense expression of the polynucleotides of the present invention; and 4) expression of the polynucleotides of the present invention in microbial hosts.

Membership in a class of proteins with a specific, substantial, and credible utility

The utility requirement for inventions relating to nucleic acid sequences can be satisfied by basing an asserted use "upon homology to existing nucleic acids or proteins having an accepted utility." *Id.* at 1096 cmt. 19.

> When a class of proteins is defined such that the members share a specific, substantial, and credible utility, the reasonable assignment of a new protein to the class of sufficiently conserved proteins would impute the same specific, substantial, and credible utility to the assigned protein. If the preponderance of the evidence of record, or of sound scientific reasoning, casts doubt upon such an asserted utility, the examiner should reject the claim for lack of utility under 35 U.S.C. 101. For example, where a class of proteins is defined by common structural features, but evidence shows that the members of the class do not share a specific, substantial functional attribute or utility, despite having structural features in common, membership in the class may

> not impute a specific, substantial, and credible utility to a new member of the class.

Id.

In the Office Action dated August 29, 2006 ("Office Action"), the "Examiner concede[d] that based on sequence homology alone instant SEQ ID NO:1 more likely than not encodes a polypeptide of SEQ ID NO:2 with sucrose transport activity." Office Action at page 2. Applicants believe that the Examiner therefore conceded that the polynucleotide sequence of the present application encodes a protein that can be reasonably assigned to a well-defined class of proteins: sucrose transporters. The Examiner went on to state, however, that assigning the claimed sequence of the current application to this class "does not provide a specific and substantial utility for the novel claimed polynucleotides." Office Action at page 3. In making this determination, the Examiner attempted to illustrate that "the preponderance of the evidence of record, or of sound scientific reasoning, casts doubt upon such an asserted utility", 66 Fed. Reg. at 1096 cmt. 19, by citing Aoki as finding that plants (that is, barley and maize) have multiple sucrose transporter genes with different expression patterns (Aoki *et al.*, 2003, Plant Cell Physiol., 44(3):223-32), and by citing Lemoine as stating that plants have multiple sucrose transporter genes with possibly distinct "exact function[s]" in plants. Lemoine, 2000, Biochim. Biophys. Acta, 1465:246-62 (*hereinafter* "Lemoine, 2000"). The Examiner also stated that the current application demonstrates "that maize has two different sucrose transporters, which may or may not have similar biological functions." Office Action at page 3.

While Applicants agree with Examiner's assertions as to the knowledge, both presently and at time of filing, of multiple sucrose transporters with different expression patterns in several plant species, Applicants respectfully submit that this does not negate the fact that, in the words of Comment 19 of the Federal Register Guidelines, "the members of the [sucrose transporter] class . . . share a specific, substantial functional attribute," namely transporting sucrose across membranes. The example given in that comment (reproduced above) illustrates that the mere presence of "common structural features" between members of a class of proteins to which the current invention has been assigned "may not impute a specific, substantial, and credible utility to a new member of the class" where "the members of

the class do not share a specific, substantial functional attribute or utility." 66. Fed. Reg. at 1096 cmt. 19. However, this same example therefore states by implication that the presence of "common structural features" coupled with a "share[d] . . . specific, substantial functional attribute" *would* "impute a specific, substantial, and credible utility to a new member of the class." Here, all members of the class of proteins to which this sequence has been assigned, sucrose transporters, share a specific and substantial functional attribute: the ability to transport sucrose across a membrane. This common functional attribute of all members of the sucrose transporter protein class has been well-known for years. *See* Lemoine, 2000, at 248-249 for a discussion of this fact; *see also* Reismeier, 1992, EMBO J., 11(13):4705-13 and Lemoine *et al.*, 1996, Plant Cell Environ., 19:1124-31 which both utilize this functional attribute of sucrose transporters to confer upon yeast mutants the ability to grow on media that contains sucrose as the sole carbon source. In fact, this is the defining characteristic of the proteins of this class, so much so that it is the basis of class member protein naming, with SUT and SUC, the two naming conventions used for class members, being abbreviation for SUcrose Transpporter and SUcrose Carrier, respectively. Lemoine, 2000, at 249. This ability to transport sucrose across a membrane is "well-defined and particular", making this a specific utility, *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005), and is "significant and presently available," i.e. a "real world" functional attribute, making this a substantial utility. *Id.* at 1376.

Further, this basic common functional attribute of all sucrose transporters confers additional utilities upon all members of this protein class. For instance, all sucrose transporters can be transformed into microbial host cells for various purposes. In one such use, transformation of a sucrose transporter into an otherwise sucrose-growth-deficient microorganism can be performed in order to confer upon that host cell the ability to grow on media containing sucrose as the sole carbon source. In fact, this ability is so ubiquitous among sucrose transporters and so well-known in the art that it has been used as a tool to functionally identify new members of the class. Demonstrating this point, Ward (1998) states in a discussion of the then-current state of the sucrose transporter art that "[c]omplementation of yeast mutants has proven to be an excellent tool to identify heterologous genes based on their function, *especially in the case of transporters.*" Ward, 1998, Int. Rev.

Cytol., 178:41-71, at 51 (emphasis added). Thus, the sucrose transporter protein class, to which SEQ ID NO:2 has been assigned, was well-known at the time of filing of the present application to be useful in conferring upon an otherwise deficient microorganism the ability to grow on media containing sucrose as its sole carbon source. Transformation of sucrose transporters into microbial hosts has additional "real world" uses, as well. For instance, U.S. Patent Number 5,750,362 (*hereinafter* "the '362 patent") utilizes transformation of various cell types, including yeast cells, with a transport protein, including sucrose transporters, in order to identify the herbicidal function of a compound. Claim 1 of this patent is directed to:

> A method for identifying substances which have a potential herbicidal or growth-regulating action which arises due to inhibition or inactivation of a plant transport process, which comprises.
>
> > a) initially preparing a transporter protein by heterologous expression of a DNA sequence which codes for said transporter protein in a transgenic plant fungus, yeast or eukaryotic cell, subsequently
> > b) employing said transgenic plant, fungus, yeast or eukaryotic cell for assaying a chemical compound for its inhibitory effect on said transporter protein, and
> > c) additionally assaying the chemical compound for activity on plant, fungus, yeast or eukaryotic cell which do not produce the corresponding transporter protein, in order to preclude the possibility that the chemical compound also has an inhibitory effect on other mechanisms in said plant, fungus, yeast or eukaryotic cell, and finally
> > d) testing the chemical compound which is active against the transporter protein for its herbicidal or growth-regulating activity on plants.

Claim 2 then narrows this scope by claiming "[a] method as claimed in claim 1, wherein the transporter is a sucrose transporter." The Specification of this patent makes no mention of particular plant sucrose transporters that should be used, instead identifying all plant sucrose transporters as useful in the invention. The '362 patent at col. 2, lines 25-29; col. 2, line 64 – col. 3, line 21; and col. 4, lines 52-57. Thus, the sucrose transporter protein class, to which SEQ ID NO:2 has been assigned, was known at the time of filing of the present application to be useful in assays for identifying herbicidal function. These examples of specific applications of the transformation of sucrose transporters into microbial host cells demonstrate that this utility of the sucrose transporter class is "well-defined and particular", making this

a specific utility, *Fisher*, 421 F.3d at 1371, and is "significant and presently available", that is, a "real world" functional attribute, making this a substantial utility. *Id.* at 1376.

An additional utility for the sucrose transporter class is demonstrated in U.S. Patent No. 6,025,544 (*hereinafter* "the '544 patent"), entitled "Processes for Modifying Plant Flowering Behavior," which issued on February 15, 2000, prior to the filing date of the present application. The '544 patent describes the creation of transgenic plants that overexpress non-endogenous sucrose transporter genes. The '544 patent, Claims 1 & 2. Claim 2 of the '544 patent reads:

> A process for modifying plant flowering behavior, comprising the steps of:
>
> > (a) transforming a plant cell with a DNA molecule which encodes in the sense orientation a sucrose carrier;
> >
> > (b) producing a transgenic plant comprising the transformed plant cell; and
> >
> > (c) growing the transgenic plant under conditions in which the DNA molecule is expressed and the transgenic plant *exhibits modified flowering behavior compared to a wildtype plants*;
> >
> > wherein expression of the DNA molecule increases the sucrose carrier activity in the transgenic plant and *wherein said modified flowering behavior comprises early flowering and flower formation.*

(emphasis added). This process is further narrowed by Claim 3, which claims "[t]he process according to Claim 2, wherein the DNA molecule encodes in the sense orientation a plant sucrose carrier." The Specification states that "the DNA molecules coding a sucrose carrier can be derived from any organism containing such sequences . . . [and] higher plants are preferred," thereby placing no limitation on the types of plant sucrose transporters that could be used in that invention. The '544 patent at col. 3, line 63 – col. 4, line 4. Thus, the sucrose transporter protein class, to which SEQ ID NO:2 has been assigned, was known at the time of filing of the present application to be useful in modifying plant flowering behavior by transformation of an exogenous plant sucrose transporter gene into a flowering plant host. This utility of the sucrose transporter class for modifying plant flowering is "well-defined and particular", making this a specific utility, *Fisher*, 421 F.3d at 1371,

and is "significant and presently available", that is a "real world" functional attribute, making this a substantial utility. *Id.* at 1376.

Further, antisense gene repression studies demonstrate that members of the sucrose transporter gene class are useful in antisense repressor systems for altering the starch content, morphology, and growth of a plant. Both before and after the filing date of this application, sucrose transporter antisense repression studies were conducted by various groups and in various plant species, all demonstrating similar results. For instance, Reismeier conducted a study in which a particular sucrose transporter gene, StSUT1, was globally repressed in the potato plant through antisense repression. Reismeier *et al.*, 1994, EMBO J., 13(1):1-7 (*hereinafter* "Reismeier, 1994"). This study concluded that such repression resulted in an increase in sucrose concentration in the leaves coupled with altered leaf morphology, plant growth retardation, and drastically reduced tuber yield. *Id.* at 2. In fact, some transformants demonstrated a <1% tuber yield compared to wild-type plants. *Id.* at 4. Similar studies were conducted with the potato plant by Kühn in 1996 and 2003. Kühn *et al.*, 1996, Plant Cell Environ., 19:1115-23; Kühn *et al.*, 2003, Plant Physiol., 131:102-13 (*hereinafter* "Kühn, 1996" and "Kühn, 2003", respectively). The earlier study again utilized global antisense repression and found, as was found by Reismeier, 1994, that repression of the sucrose transporter gene resulted in an altered leaf morphology, plant growth retardation, and reduced tuber yield. Kühn, 1996 at 1117. In contrast, the later study utilized tuber-tissue-specific antisense repression of the sucrose transporter gene. Kühn, 2003, at 104. This repression resulted in "no detectable changes in the phenotype of the aerial parts of the plant," e.g. the leaves, but readily detectable changes in the part of the plant affected containing the gene repression, as evidenced by a greatly reduced tuber yield. *Id.* Similarly, Bürkle conducted an antisense repression study in the tobacco plant using the sucrose transporter gene NtSUT1. Bürkle *et al.*, 1998, Plant Physiol., 118:59-68 (*hereinafter* "Bürkle, 1998"). Consistent with the potato studies, this study found that repression resulted in altered leaf morphology, retarded plant growth, retarded flowering, and altered starch content of the plant. *Id.* at 62-64. Lastly, Scofield conducted a study of antisense repression of the sucrose transporter OsSUT1 in rice. Scofield *et al.*, 2002, Funct. Plant Biol., 29:815-26 (*hereinafter* "Scofield, 2002"). This study found that such sucrose transporter repression resulted

in decreased grain fill/yield, reduced rate of germination and growth, and an altered starch content of the plant. *Id.* at 817-23. While the results of these sucrose transporter repression studies were not absolutely identical, they were relatively consistent in that they resulted in altered starch content, plant morphology, and plant growth characteristics. Thus, the sucrose transporter protein class, to which SEQ ID NO:2 has been assigned, was known at the time of filing of the present application to be useful in antisense repression systems to alter the starch content, morphology, and growth characteristics of a plant. This utility of the sucrose transport protein class for altering the starch content, morphology, and growth characteristics of a plant is "well-defined and particular", making this a specific utility, *Fisher*, 421 F.3d at 1371, and is "significant and presently available", that is a "real world" functional attribute, making this a substantial utility. *Id.* at 1376.

Applicants therefore contend that, despite their having differential expression patterns, members of the sucrose transporter protein class all "share a specific, substantial functional attribute or utility," which therefore makes assignment of a protein to this class a sufficient assertion of utility under 35 U.S.C. § 101. 66 Fed. Reg. at 1096 cmt. 19. Applicants therefore submit that assignment of SEQ ID NO:2 to this class of proteins, which Examiner concedes is appropriate, Office Action at page 2, constitutes an assertion of a specific, substantial, and credible utility for the present invention, and therefore respectfully request that this rejection be withdrawn and all claims allowed.

Non-endogenous expression of polynucleotides of the present invention

A second utility of the present invention that is asserted by Applicants and disclosed in the Specification is expression of the polynucleotides of the instant invention in a non-endogenous plant. Specification, page 11, line 30 – page 12, line 11; Examples 4 & 5. The Examiner conceded at page 2 of the Office Action, that Applicants adequately disclosed such non-endogenous expression, but contended that "the specification does not provide a specific and substantial utility for such non-endogenous expression." Office Action at page 3.

Applicants respectfully submit, however, that the then-current state of the art made it well-known to those of ordinary skill in the art that such non-endogenous expression would lead to altered flowering characteristics of the transgenic plants,

which is a specific and substantial utility. That this was known at the time of the application is evidenced by the '544 patent. As discussed above, the '544 patent describes the creation of transgenic plants that overexpress non-endogenous sucrose transporter genes. The '544 patent, Claims 1 & 2. Such transgenic plant creation is also described in the Specification of the present application. Specification, page 11, line 30 – page 12, line 11; Examples 4 & 5. The '544 patent then goes on to disclose that such overexpression will result in "modified flowering behavior compared to wildtype plants . . . wherein said modified flowering behavior comprises early flowering and flower formation." The '544 patent, Claim 1. The '544 patent further states that "the DNA molecules coding a sucrose carrier can be derived from any organism containing such sequences . . . [and] higher plants are preferred." *Id.* at col. 3, line 63 – col. 4, line 4. As the '544 patent places no limitation on the types of sucrose transporters that could be used in that invention, and as the Examiner conceded that the polynucleotide of the present invention more likely than not encodes a sucrose transporter, Office Action at page 2, it would be clear to those of ordinary skill in the art at the time of filing of the present application that the polynucleotide of the present invention could be used to alter flowering behavior of plants. Such a use for the present invention "provide[s a] well-defined and particular benefit to the public" which is "significant and presently available . . . to the public," thereby making this is a specific, substantial, and credible use for the present invention.

Further, even if the Examiner finds the disclosure of such utility in the Specification to be insufficient, Applicants contend that use of the present invention in transgenic plant creation so as to alter flowering behavior is a well-established utility for the sucrose transporter of the present application in light of the '544 patent discussed above: "a person of ordinary skill in the art would immediately appreciate" that the invention could be used to alter flowering behavior of plants, which is a "specific, substantial, and credible" utility. MPEP § 2107(II)(A)(3).

Thus, Applicants respectfully submit that non-endogenous expression of polynucleotides of the present invention is both a disclosed and a well-established specific, substantial, and credible utility for the present invention, thereby overcoming the rejection for lack of utility under 35 U.S.C. § 101. Applicants therefore respectfully request that this rejection be withdrawn and all claims allowed.

Antisense expression of the polynucleotides of the present invention

Another utility of the present invention that is asserted by Applicants and disclosed in the Specification is use of the claimed polynucleotides in the design of antisense constructs and the transformation of such constructs into plant cells in order to repress activity of the endogenous sucrose transporter gene. Specification, page 12, lines 22-30. The Examiner contended that such a disclosure does not constitute disclosure of a specific, substantial, and credible utility. Office Action at pages 4-5. This contention is essentially based upon the assertion that the specific result of antisense gene repression of the polynucleotide sequence of the present invention has not been demonstrated. However, Applicants contend that, given the state of the art and the totality of available references at the time the present application was filed, such a utility for the claimed invention is both specific and substantial.

In the previous response, Applicants stated that antisense repression using the polynucleotides of the present invention could, for example, impact grain filling, as was found for the rice sucrose transporter OsSUT1 by Scofield, 2002. June 12, 2006, Response at pages 5-6. The Examiner found this argument unpersuasive and determined that Scofield, 2002 did not teach the claimed sequence of the present invention. Office Action at pages 4-5. However, Applicants respectfully submit that the Examiner read too narrowly the specific, substantial, and credible utility that Applicants were and are asserting. While Scofield, 2002 alone discusses only impaired grain filling resulting from antisense repression of the OsSUT1 sucrose transporter gene, Applicants were utilizing this reference merely as one example of the type of results consistently observed from antisense repression of sucrose transporters in general. Scofield, 2002, coupled with the several other sucrose transporter antisense repression studies conducted both before and after the filing of the present application, demonstrates that there is a predictable result that arises from antisense repression of any sucrose transporter that would have been well-known to those of ordinary skill in the art at the time of filing, namely alteration of the affected plant's starch content, morphology, and growth characteristics. The references demonstrating this consistent result are discussed in detail above and will therefore not be discussed in detail again here. However, as a brief summary,

Reismeier, 1994, Kühn, 1996, and Kühn, 2003 found that antisense repression of a sucrose transporter in the potato plant caused altered starch content and decreased plant growth and tuber mass; Bürkle, 1998 found that such repression in the tobacco plant caused altered starch content and decreased plant growth; and Scofield, 2002 found that such repression in the rice plant caused altered starch content, reduced grain yield, and reduced rate of germination and growth. Thus, while the results of sucrose transporter repression in these various species were not absolutely identical, they were relatively consistent. Given this consistent result of antisense repression of sucrose transporter genes, those skilled in the art would have understood that the use of the polynucleotides of the present invention in an antisense repression system, as disclosed in the Specification, would more likely than not have caused altered plant starch content and growth characteristics. Such a use for the present invention "provide[s a] well-defined and particular benefit to the public" which is "significant and presently available . . . to the public," thereby making this is a specific, substantial, and credible use for the present invention.

Further, even if the Examiner finds the disclosure of such utility in the Specification to be insufficient, Applicants contend that use of the polynucleotides of the present invention in antisense repression of sucrose transporter genes so as to alter plant starch content and growth characteristics is a well-established utility for the sucrose transporter of the present invention in light of the several published studies demonstrating the consistent results of sucrose transporter repression: "a person of ordinary skill in the art would immediately appreciate" that the invention could be used in antisense repression to alter plant starch content and growth, which is a "specific, substantial, and credible" utility. MPEP § 2107(II)(A)(3).

Thus, Applicants respectfully submit that use of the polynucleotides of the present invention in antisense repression is both a disclosed and a well-established specific, substantial, and credible utility for the present invention, thereby overcoming the rejection for lack of utility under 35 U.S.C. § 101. Applicants therefore respectfully request that this rejection be withdrawn and all claims allowed.

Expression of the polynucleotides of the present invention in microbial hosts

A further utility asserted by Applicants and disclosed by the Specification of the present invention that will be herein discussed is expression of the claimed

polynucleotides in microbial host cells. Specification, page 23, line 21 – page 24, line 23. Applicants contend that, given the state of the art at the time the present application was filed, such a disclosure would constitute disclosure of a specific, substantial, and credible utility for the claimed invention.

Expression of the polynucleotides of the current invention in microbial hosts would be useful in the method of the '362 patent, which was issued prior to the filing date of the present application and which relates to "Methods for Identifying Substances with a Potential Herbicidal or Growth-Regulating Action by Means of Plant Transporter Proteins." As discussed above, the '362 patent claims a method involving transformation of various host cells, including microbial hosts (e.g. yeast), with various types of genes, including plant sucrose transporter genes, in order to identify the herbicidal function of a compound. The '362 patent, Claims 1-2. The '362 patent makes no mention of particular plant sucrose transporters that should be used, instead identifying all plant sucrose transporters as useful in the invention. The '362 patent at col. 2, lines 25-29; col. 2, line 64 – col. 3, line 21; and col. 4, lines 52-57. Thus, given the disclosure of transformation of microbial cells with the polynucleotide sequences of the present invention, it would be clear and well-known to those of ordinary skill in the art that the presently claimed polynucleotide of could be used to identify the herbicidal function of a compound. Such a use for the present invention "provide[s a] well-defined and particular benefit to the public" which is "significant and presently available . . . to the public," thereby making this is a specific, substantial, and credible use for the present invention.

Further, even if the Examiner finds the disclosure of such utility in the Specification to be insufficient, Applicants contend that, given the existence of the '362 patent, identification of the herbicidal function of a compound through the creation of transformed microbial host cells is a well-established use of the present invention: "a person of ordinary skill in the art would immediately appreciate" that the invention could be used to transform microbial host cells and thereby identify the herbicidal function of a compound, which is a "specific, substantial, and credible" utility. MPEP § 2107(II)(A)(3).

Thus, Applicants respectfully submit that expression of the polynucleotides of the present invention in microbial host cells is both a disclosed and a well-established specific, substantial, and credible utility for the present invention, thereby

overcoming the rejection for lack of utility under 35 U.S.C. § 101. Applicants therefore respectfully request that this rejection be withdrawn and all claims allowed.

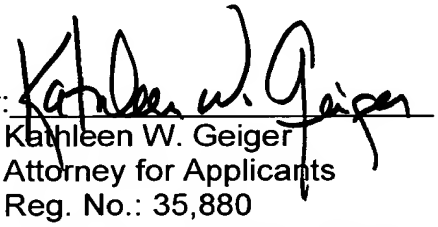
Rejections Under 35 U.S.C. § 112, 1st Paragraph

Claims 25, 27-30, 32, and 34 were rejected under 35 U.S.C. § 112, 1st Paragraph, as failing to comply with the enablement requirement. The Examiner asserted that, because the claimed invention is not supported by either a substantial asserted utility or a well-established utility, one skilled in the art would not know how to use the claimed invention. Applicants respectfully submit that, because the utility rejection above has been traversed, the rejections under 35 U.S.C. § 112, 1st Paragraph, have also been traversed and therefore request that these rejections be withdrawn and the claims allowed.

Summary

In view of the foregoing remarks, Applicants submit that this application is in condition for allowance. In order to expedite disposition of this case, the Examiner is invited to contact Applicants' representative at the telephone number below to resolve any remaining issues. Should there be a fee due which is not accounted for, please charge such fee to Deposit Account No. 501447 (Potter Anderson & Corroon LLP).

Respectfully submitted,

By: 

Kathleen W. Geiger
Attorney for Applicants
Reg. No.: 35,880
Telephone: (302) 984-6075
Facsimile: (302) 658-1192

Dated: February 27, 2007